APR 2 8 2003

K030585

Section 6-1

Bisco, Inc.
1100 W. Irving Park Road, Schaumburg, IL. 60193
U.S.A.
Telephone: (847) 534-6000 or 1-800-BIS-DENT Fax: (847) 534-6396
WEB SITE http://www.bisco.com

Contact: Stephen D. Smith

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 190 and 21 CFR par 807.92

Trade Name: **SCULPTING RESIN**
Common Name: Wetting Resin
Classification name: Material, Tooth Shade, Resin
Class II per 21 CFR 872.3690

Description of Applicant Device:
SCULPTING RESIN is a light-cured, low viscosity micro filled (30% by weight) resin formulation for use as a composite sculpting resin. It is supplied in a bottle and syringe. It is used on an instrument to reduce tackiness when shaping composites.

Intended uses of Applicant Device:
BISCO SCULPTING RESIN is for use as a composite wetting resin.

Predicate Devices: ULTRADENT COMPOSITE WETTING RESIN

Significant Performance Characteristics:

	BISCO SCULPTING RESIN	**ULTRADENT COMPOSITE WETTING RESIN**
Intended Use	Wetting resin.	Wetting resin.
Product Description	Light-cured, low viscosity (30% filled), Methacrylates resin for use as a composite sculpting resin	Light cured, low viscosity (45% filled), Methacrylates resin used as a composite sculpting resin
Delivery System	Bottle and syringe	Syringe

Side by side comparisons of SCULPTING RESIN to the predicate device ULTRADENT COMPOSITE WETTING RESIN clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. SCULPTING RESIN was tested for biocompatibility and was found to be non-toxic.
It is concluded that the information supplied in this submission has proven the safety and efficacy of SCULPTING RESIN.

Stephen D. Smith
Manager Regulatory Affairs
Telephone: 847 534-6146
Fax: 847-534-6396

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2003

Mr. Steve Smith
Manager of Regulatory Affairs
Bisco, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K030585
Trade/Device Name: Sculpting Resin
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: February 21, 2003
Received: February 24, 2003

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

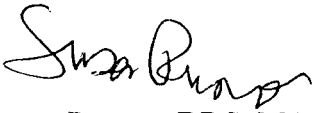
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030585

Device Name: **Sculpting Resin**

Indications For Use:

The intended use of Bisco's Sculpting Resin is as a pre-wetting agent for placing and sculpting layers of composites and between layers of cured composite

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030585